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| APPLICATION NO.             | FILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------------------|--|----------------------|-------------------------|------------------|
| 10/800,179                  | 03/12/2004 Manoj Kumar DOC0057PA/DC5074/GC792-4 8989 |                      | 4 8989                  |                  |
| 75                          | 90 07/21/2005  |                      | EXAM                    | INER             |
| DINSMORE & SHOHL LLP        |  |                      | KOSAR, ANDREW D         |                  |
| One Dayton Centre Suite 500 |  |                      | ART UNIT                | PAPER NUMBER     |
| One South Main Street       |  |                      | 1654                    |                  |
| Dayton, OH 45402-2023       |  |                      | DATE MAILED: 07/21/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.                    | Applicant(s)            |  |  |  |
|---|---|------------------------------------|-------------------------|--|--|--|
| Office Action Summary   |   | 10/800,179                         | KUMAR ET AL.            |  |  |  |
|   |   | Examiner                           | Art Unit                |  |  |  |
|   |   | Andrew D. Kosar                    | 1654                    |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                                    |                         |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                    |                         |  |  |  |
| Status  | ·   |                                    |                         |  |  |  |
| 1)🖂   | 1) Responsive to communication(s) filed on 27 April 2005.   |                                    |                         |  |  |  |
| 2a)⊠  | This action is <b>FINAL</b> . 2b) Th  | is action is non-final.            |                         |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                                    |                         |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                       |                                    |                         |  |  |  |
| Disposition of Claims   |   |                                    |                         |  |  |  |
| 4)⊠ Claim(s) <u>1-33</u> is/are pending in the application.   |   |                                    |                         |  |  |  |
|   | 4a) Of the above claim(s) <u>5-7,10,11,16-30,32 and 33</u> is/are withdrawn from consideration.                 |                                    |                         |  |  |  |
| 5)[   | 5) Claim(s) is/are allowed.   |                                    |                         |  |  |  |
|   | ☑ Claim(s) <u>1-4,8,9,12-14 and 31</u> is/are rejected.   |                                    |                         |  |  |  |
| · · · · · ·   | Claim(s) <u>15</u> is/are objected to.  |                                    |                         |  |  |  |
| .8)∟  | Claim(s) are subject to restriction and   | or election requirement.           | ·                       |  |  |  |
| Application Papers  |   |                                    |                         |  |  |  |
| 9)  | The specification is objected to by the Examir  | ner.                               |                         |  |  |  |
| 10)⊠  | The drawing(s) filed on 27 April 2005 is/are:   | a)⊠ accepted or b)⊡ objected to    | by the Examiner.        |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                                    |                         |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |                                    |                         |  |  |  |
| 11)   | The oath or declaration is objected to by the l   | examiner. Note the attached Office | Action or form PTO-152. |  |  |  |
| Priority u  | inder 35 U.S.C. § 119   | •                                  |                         |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:  |   |                                    |                         |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                                    |                         |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                                    |                         |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |                                    |                         |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |                                    |                         |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |                                    |                         |  |  |  |
|   |   |                                    |                         |  |  |  |
| Attachment(s)   |   |                                    |                         |  |  |  |
| 1) 🛛 Notic  | e of References Cited (PTO-892)   | 4) Interview Summary               |                         |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) Paper No(s)/Mail Date   |   |                                    |                         |  |  |  |

## **DETAILED ACTION**

Claims 1-33 are pending.

## Response to Arguments/Amendments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not specifically addressed is herein withdrawn.

Applicant's amendments filed April 27, 2005 are acknowledged.

Applicant's amendments to the drawings are accepted.

Claims 1 and 3 stand rejected under 35 USC § 102(b) as anticipated by Coleman. Claim 1 stands rejected under 35 USC § 112, 1<sup>st</sup> paragraph, as lacking written description.

Claims 2, 4-14, and 16-33 stand withdrawn as non-elected inventions and/or species, there being no allowable generic or linking claim.

Claim 15 stands as objected to as depending from a rejected claim.

Applicant's arguments filed April 27, 2005, with respect to the rejection(s) of claim(s) 1 and 3 under 35 USC § 102(b), and claim 1 under 35 USC § 112, 1<sup>st</sup> paragraph, have been fully considered and are persuasive, upon Applicants amendment to the claims. Therefore, the rejection has been withdrawn. However, a new ground(s) of rejection is set forth below, necessitated by Applicant's amendments.

The examiner has extended the search to the peptide/protein collagen. Applicant states,

Specifically, there are more than six hundred repeating amino acid sequence units known to exist in biological systems. For example, well known proteins containing repeating amino acid sequence units include abductin, elastin, byssus, flagelliform silk, dragline silk, gluten high molecular weight (HMW) subunit, titin, fibronectin, leminin, and collagen.

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Individual repeating amino acid sequence units of particular interest include units found in silk-, elastin-, collagen-, abductin-, byssus-, gluten-, titin-. extensin-, and fibronectin-like proteins. Silk-like proteins comprise a repeating sequence unit SGAGAG (SEQ ID NO. 1). This repeating sequence unit is found in naturally occurring silk fibroin protein, which can be represented as GAGAGISGAGAGISSGAAGY (SEQ m NO. 2). Elastin-like proteins comprise a base repeating 'sequence unit of GVGVP (SEQ m NO. 3). This repeating sequence unit may be found in naturally occurring elastin. Collagen-like 1) proteins comprise a repeating sequence unit of G-X-X<sup>1</sup>, wherein X comprises any amino acid, X<sup>1</sup> comprises any amino acid, often proline or hydroxy-proline (SEQ ID NO:20). (page 4, Specification).

Collagen comprises the sequence:

XGPIGXXGPRGRTGDAGPAGPXGPXGPXGPXGPP, where X is hydroxyproline.

The personal care composition comprising collagen is readable upon claims 1-4, 8, 9, 12-14 and 31.

Claims 5-7, 10, 11, 16-30, 32, and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 1, 2004.

#### Claim Rejections - 35 USC § 102

Claims 1-4, 8, 9, 12-14, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by WOLFINBARGER (US PGPUB 2002/0147154 A1) in view of VOET (D. Voet and J.G. Voet, in Biochemistry, 2<sup>nd</sup> Ed. (1995)).

The claims are drawn to repeat sequence protein polymers.

Voet teaches that collagen comprises the sequence:

GL[(XGPIGXXGPRGRTGD)(AGP)<sub>2</sub>(XGP)<sub>4</sub>]P (page 158, Figure 7-30).

The sequence meets the instant claim limitations as follows:

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T <u>comprises</u> all amino acids in collagen through GL, T' <u>comprises</u> all amino acids in collagen from P through the end of the sequence, y and y' are each 1;

 $A_n$  is XGPIGXXGPRGRTGD, n is 15, x is 1;  $A'_{n'}$  is AGP, n is 3, x is 2;  $A''_{n''}$  is XGP, n is 3, x is 4; and i is 1.

Because the sequence of T and T' <u>comprise</u> amino acid sequences, it is not limited to the length of from 1 to 100 amino acids, as would be the case with <u>consisting of 1</u> to 100 amino acids, and thus embraces any peptidic component greater than or equal to 1 amino acid.

Wolfinbarger teaches a cosmetic composition, comprising marine invertebrate type V telopeptide containing collagen (claim 1), where the collagen is present in an amount of from 0.001 wt % to 30 wt % (claim 4), 0.1 wt % to 10 wt % (claim 5), or 0.2 wt % to 5 wt % (claim 6).

Wolfinbarger teaches a cream rinse hair-conditioner with collagen gelatin solution at 0.2 w/w % (Example 10, page 9). The cream rinse comprises carriers and excipients, e.g., cetyl alcohol, dimethicone, xanthan gum, water, and stearic acid. (Example 10).

### Allowable Subject Matter

Claim 15 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

SILVER (US Patent 5,196,185) teaches methods of wound treatment via administration of collagen particles, fibronectin, and laminin.

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LUBOWE (US Patent 4,474,763) teaches skin preparations comprising elastin, and additional ingredients such as collagen.

SHARMA (US Patent 5,672,336) teaches wound dressings comprising particulate collagen

PANG (US PGPUB 2003/0124152 A1) teaches decorin in cosmetic compositions.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.

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